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EXAMINER

MULCAHY, JOHN M

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 07/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/660,840

Applicant(s)

REMIJAN ET AL.

Examiner

John M. Mulcahy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-80 is/are pending in the application.
- 4a) Of the above claim(s) 19-21, 34, 40-50, 52-58 and 70-80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 22-33, 35-39, 51 and 59-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Election/Restrictions

1. Applicant's election without traverse of claims 1-18, 22-33, 35-39, 51, 52, and 54-69 in Paper No. 10 is acknowledged. Claims 19-21, 34, 40-50, 52, 53-58* and 70-80 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claim Objections

2. Claim 67 is objected to because of the following informalities: in line 1, --the-- should be inserted before "waveguide."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-12, 39, 64 and 67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 7-9, "the light absorbing sheath" lacks antecedent in the "light absorbing layer" of claim 1.

* Although Applicant lists claims 52 and 54-58 as reading on the elected species, such claims are drawn to the non-elected species of combined light and image guide since the claimed subject matter is only disclosed for use with such embodiments.

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In claims 10-12, "the illumination channel" lacks antecedent in claim 1. In action on the merits, these claims were interpreted as depending from claim 4, which provides proper antecedent.

In claim 39, recitation of "a rigid channel *having connected* to the handle with a coupler" is indefinite. Inasmuch as the metes and bounds of this claim could only be guessed at, it has not been further treated on the merits.

In claim 64, "the sheath" lacks antecedent in claim 53. In action on the merits, this claim was interpreted as depending from claim 63 as is believed to have been intended.

In claim 67, "the cannula" lacks antecedent in claim 51. In action on the merits, this claim was interpreted as depending from claim 66 as is believed to have been intended.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

As to the elected claims, the Examiner takes official notice that a miniature endoscope (hereinafter "the noticed endoscope") comprising:

As to claim 1: an optical waveguide that transmits an image; an optical element coupled to a distal end of the waveguide; an optical relay that is optically

coupled to a proximal end of the waveguide; and an imaging device mounted at a proximal end of the optical relay that receives an image from the optical waveguide;

As to claim 4: further comprising an illumination channel;

As to claim 6: wherein the waveguide comprises a glass rod;

As to claim 12: wherein the illumination channel further comprises an outer sheath;

As to claim 15: wherein the optical element comprises one or more lenses;

As to claim 16: wherein the optical element comprises a plastic lens;

As to claim 17: wherein the imaging device comprises a charge coupled device;

As to claim 22: further comprising a handle in which the optical relay and imaging device are positioned;

As to claim 23: further comprising an illumination channel that is optically coupled to a light source in the handle;

As to claim 27: further comprising a light source that is optically coupled to the optical waveguide;

was notoriously old and well known at the time of invention.

a. Claims 1, 2, 6, 15-17, 22, 23 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over the noticed endoscope in view of Yoshida et al. (4,593,973).

The noticed endoscope fails to show a light absorbing layer (claim 1). However, Yoshida et al. shows an analogous endoscope utilizing an image guide 5 having a light

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absorbing layer 13. It would have been obvious to the artisan to modify the noticed endoscope by utilizing an image guide having a light absorbing layer since Yoshida et al. teaches that such would transmit a suitable image.

The noticed endoscope further fails to show the image waveguide having a diameter of less than 2 mm (claim 1) in an endoscope having an outer diameter of 1.6 mm or less (claim 2). However, Yoshida et al. teaches an analogous endoscope having waveguide and endoscope diameters in the claimed range (col. 4, line 6). It would have been obvious to the artisan to modify the noticed endoscope by fitting the waveguide and endoscope diameters to the claimed range since Yoshida et al. suggests such would be suitable for dental surgery.

b. Claims 1, 3, 6, 15-17, 22, 23 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over the noticed endoscope in view of Yoshida et al. (4,593,973) and Goldenberg (4,641,912).

The noticed endoscope fails to show a light absorbing layer. However, Yoshida et al. shows an analogous endoscope utilizing an image guide 5 having a light absorbing layer 13. It would have been obvious to the artisan to modify the noticed endoscope by utilizing an image guide having a light absorbing layer since Yoshida et al. teaches that such would transmit a suitable image.

The noticed endoscope fails to show the image waveguide having a diameter of less than 2 mm (claim 1), specifically between 0.6 and 1.6 mm (claim 3). However, Goldenberg teaches an analogous endoscope having an image guide with a diameter in the claimed range (1 mm: see col. 7, lines 50-51). It would have been obvious to the

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artisan to modify the noticed endoscope by using a waveguide having a diameter in the claimed range since Goldenberg suggest that such would be suitable for use in angioplasty.

c. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over the noticed endoscope in view of Yoshida et al. (4,593,973) as applied to claim 1 above, further in view of Anapliotis et al. (5,184,602).

The noticed endoscope fails to teach a binary phase ring for the illumination channel. However, Anapliotis et al. teaches an analogous endoscope having such a ring 130. It would have been obvious to the artisan to further modify the noticed endoscope by adding such a ring since Anapliotis et al. suggest that such would improve the illumination.

d. Claims 5, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over the noticed endoscope in view of Yoshida et al. (4,593,973) as applied to claim 1 above, further in view of Araujo et al. (3,784,386).

Yoshida et al. fails to specify the refractive index of the waveguide (claim 5) or that the light absorbing layer comprises extramural absorption glass (claim 8) or has a refractive index of 1.6 or less (claim 9). However, Araujo et al. teaches an analogous imaging fiber wherein the waveguide comprises a glass having a refractive index in the claimed range (above 1.6: see col. 4, lines 66-67) and the light absorbing layer comprises extramural absorption glass (col. 7, lines 9-12) having a refractive index of 1.6 or less (col. 4, lines 66-67). It would have been obvious to the artisan to further modify the noticed endoscope by using a waveguide having the claimed properties

since Araujo et al. teach such to be advantageous (see the "Background" and "Summary" of the invention).

e. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over the noticed endoscope in view of Yoshida et al. (4,593,973) as applied to claim 1 above; Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over the noticed endoscope in view of Yoshida et al. (4,593,973) and Anapliotis et al. (5,184,602) as applied to claim 4 above.

Yoshida et al. fails to specify the thickness of the light absorbing layer and the noticed endoscope fails to show the claimed wall thickness of the illumination channel. However, inasmuch as neither Applicant nor the prior art of record attribute any significance to the precise thicknesses of these layers (Applicant discloses the claimed ranges simply as preferred), the choice of such thicknesses would have been obvious to the artisan if routine experimentation proved such to be suitable. Where the instant specification and evidence of record fail to attribute any significance (novel or unexpected results) to a particular arrangement, the particular arrangement is deemed to have been an obvious modification. In re Kuhle, 526 F.2d 553, 555, 188 USPQ 7, 9 (CCPA 1975).

f. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over the noticed endoscope in view of Yoshida et al. (4,593,973) and Anapliotis et al. (5,184,602) as applied to claim 4 above, further in view of Strack (3,902,880).

The noticed endoscope fails to teach an illumination channel having the claimed refractive index. However, Strack teaches an analogous endoscope having an

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illumination channel 28 with a refractive index in the claimed range (1.5-1.6: see col. 3, lines 12-17). It would have been obvious to the artisan to further modify the noticed endoscope by using an illumination channel having a refractive index in the claimed range since Strack suggests that such would provide proper illumination.

g. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over the noticed endoscope in view of Yoshida et al. (4,593,973), Anaplotis et al. (5,184,602) and Strack (3,902,880) as applied to claim 4 above, further in view of the Examiner's official notice.

The noticed endoscope fails to show a polyamide outer sheath. However, the Examiner takes official notice that such coatings were notoriously old and well known in the endoscope art at the time of the invention. It would have been obvious to the artisan to modify the noticed endoscope by adding a polyamide coating to the illumination channel since such coating was well known to be suitable.

As to claim 14: Inasmuch as neither Applicant nor the prior art of record attribute any significance to the precise thickness of the coating (Applicant discloses the claimed ranges simply as preferred), the choice of such thickness would have been obvious to the artisan if routine experimentation proved such to be suitable. Where the instant specification and evidence of record fail to attribute any significance (novel or unexpected results) to a particular arrangement, the particular arrangement is deemed to have been an obvious modification. In re Kuhle, 526 F.2d 553, 555, 188 USPQ 7, 9 (CCPA 1975).

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h. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over the noticed endoscope in view of Yoshida et al. (4,593,973) as applied to claim 1 above, further in view of Olinger et al. (3,941,121).

The noticed endoscope fails to show a distal needle that penetrates tissue. However, Olinger et al. shows an analogous endoscope having a distal needle 11. It would have been obvious to the artisan to further modify the noticed endoscope by adding a distal needle as claimed since Olinger et al. teach that such would allow access to more areas of the body.

i. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over the noticed endoscope in view of Yoshida et al. (4,593,973) as applied to claim 22 above, further in view of Yarush et al. (5,879,289).

The noticed endoscope fails to show a light source in the handle. However, Yarush et al. shows an analogous endoscope having a light source 94 in the handle. It would have been obvious to the artisan to further modify the noticed endoscope by placing the light source in the handle since Yarush et al. teaches that such would be more convenient for the surgeon.

j. Claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over the noticed endoscope in view of Yoshida et al. (4,593,973) as applied to claim 22 above, further in view of Kurtzer (5,168,863).

The noticed endoscope fails to show:

As to claim 24: a coupler that connects the handle to the optical waveguide. However, Kurtzer shows an analogous endoscope having such a coupler 12. It would

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have been obvious to the artisan to further modify the noticed endoscope by utilizing such a coupler since such would allow the camera to be used with the diverse waveguides, thus allowing hospitals to obtain a full line of endoscopes at less expense.

As to claim 25: a disposable sheath that extends over the handle of the endoscope. However, Kurtzer shows an analogous sheath 20 that extends over the handle of an endoscope. It would have been obvious to the artisan to further modify the noticed endoscope by adding a sheath extending over the handle since Kurtzer suggests that such would protect the handle from contamination.

As to claim 26: that the sheath is attached to a rigid waveguide housing that is connected to the handle. However, Kurtzer's sheath is attached to a rigid waveguide housing 46. See the embodiment of Fig. 6; note col. 6, line 39. It would have been obvious to the artisan to further modify the noticed endoscope by attaching the sheath to the rigid waveguide since Kurtzer teaches that such would provide a suitably sterile barrier.

k. Claims 28, 29, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida et al. (4,593,973) in view of the Examiner's official notice.

Yoshida et al. shows an endoscope comprising:

As to claim 28: an imaging channel 5 having a diameter less than 2 mm (col. 4, line 6) and a light absorbing layer 13 defining a channel boundary; an illumination channel 12 having a first layer on an inner surface of the illumination channel and a second layer on an outer surface of the illumination channel (col.

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3, lines 5-9); an optical element coupled to a distal end of the imaging channel (col. 1, line 19).

As to claim 35: the illumination channel is coupled to a light source 1.

As to claim 36: the illumination channel comprises a material having a refractive index higher than the first layer and the second layer (col. 3, lines 4-9).

Yoshida et al. fails to show an optical relay coupled to a proximal end of the imaging channel (claim 28); and a CCD (claim 29) imaging device (claim 28) coupled to a proximal end of the optical relay. However, the Examiner takes official notice that it was notoriously old and well known to provide analogous endoscopes with proximal optical relays and CCDs. It would have been obvious to the artisan to modify Yoshida et al. by adding such features since, e.g., such would allow the surgeon to record the surgery for later study.

I. Claims 30, 33, 37 and 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida et al. (4,593,973) in view of the Examiner's official notice as applied to claim 28 above, further in view of Araujo et al. (3,784,386).

Yoshida et al. fails to specify the refractive index of the imaging channel (claim 30) or that the light absorbing layer comprises a light absorbing glass (claim 33) or the refractive index of the illumination channel (claim 37) or the layers (claim 38). However, Araujo et al. teaches an analogous fiber wherein the waveguide comprises a glass having a refractive index in the claimed range (above 1.6: see col. 4, lines 66-67) and the light absorbing layer comprises extramural absorption glass (col. 7, lines 9-12) having a refractive index less than 1.6 (col. 4, lines 66-67). It would have been obvious

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to the artisan to further modify Yoshida et al. by using a waveguide having the claimed properties for either the imaging or illumination channels since Araujo et al. teach such to be advantageous (see the "Background" and "Summary" of the invention).

m. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida et al. (4,593,973) in view of the Examiner's official notice and Araujo et al. (3,784,386) as applied to claim 30 above, further in view of the Examiner's official notice.

Yoshida et al. fails to show the imaging light channel comprises a glass rod. However, the Examiner takes official notice that it was notoriously old and well known in the endoscope art to employ a glass rod for the imaging channel. It would have been obvious to the artisan to modify Yoshida et al. by employing a glass rod in place of the disclosed fiber in order to take advantage of the known properties of such glass rod imaging channels.

n. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida et al. (4,593,973) in view of the Examiner's official notice and Araujo et al. (3,784,386) as applied to claim 31 above, further in view of Nishioka et al. (5,479,550).

Yoshida et al. fails to specify an F2 or F7 glass imaging channel. However, Nishioka et al. shows an analogous imaging channel using an F2 glass (ninth embodiment). It would have been obvious to the artisan to modify Yoshida et al. by choosing such material since Nishioka et al. teaches such to be suitable for an imaging channel.

As to claim 32: The miniature endoscope of Claim 31 wherein the glass rod comprises an F2 or an F7 glass.

As to claim 33: The miniature endoscope of Claim 28 wherein the light absorbing layer comprises a light absorbing glass.

As to claim 37: The miniature endoscope of Claim 28 wherein the illumination channel comprises a transparent material having a refractive index of at least 1.6.

As to claim 38: The miniature endoscope of Claim 28 wherein the first layer and the second layer each have index of refraction of less than 1.6.

o. Claims 51, 59-61 and 66-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hosaka et al. (EP 0,461,669) in view of Yoshida et al. (4,59,973).

Hosaka et al. shows an endoscope comprising:

As to claim 51: a handle 13 having an imaging device 14, a light source 19 and a first coupling element 13b; a rigid probe 1 having a waveguide 2 and a second coupling element 3a that connects the probe to the first coupling element.

As to claim 59: wherein the light source is coupled to an illumination channel 9 with a fiber optic element 20.

As to claim 60: wherein the probe comprises an annular illumination channel around the waveguide (Fig. 2).

As to claim 61: wherein the light source comprises an external lamp (not shown: col. 3, line 20).

As to claim 66: further comprising a cannula 8 wherein the probe fits within the cannula.

As to claim 67: wherein the waveguide comprises a rod and lens assembly 2, 4 having a locking mechanism 6 wherein the cannula locks onto the rod and lens assembly.

As to claim 68: wherein the cannula comprises an illumination channel 9.

Hosaka et al. fails to show the waveguide having a light absorbing boundary. However, Yoshida et al. shows an analogous endoscope having a waveguide 5 with a light absorbing boundary 13. It would have been obvious to the artisan to modify Hosaka et al. by utilizing a waveguide having a light absorbing boundary as taught by Yoshida et al. since Yoshida et al. suggest that such would transmit a suitable image.

p. Claim 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hosaka et al. (EP 0,461,669) in view of Yoshida et al. (4,59,973) as applied to claim 51 above, further in view of Takami (4,963,960).

Hosaka et al. fails to show a xenon light source. However, Takami shows an analogous endoscope which uses a xenon light source. It would have been obvious to the artisan to modify Hosaka et al. by using a xenon light source since Takami suggests that such would provide suitable illumination.

q. Claims 63 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hosaka et al. (EP 0,461,669) in view of Yoshida et al. (4,59,973) as applied to claim 51 above, further in view of Kurtzer (5,168,863).

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Hosaka et al. fails to show a sterile sheath attached to the probe and extending over the handle. However, Kurtzer shows an analogous endoscope having such a sheath. It would have been obvious to the artisan to further modify Hosaka et al. by adding a sheath as taught by Kurtzer since Kurtzer teaches that such would prevent contamination.

r. Claim 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hosaka et al. (EP 0,461,669) in view of Yoshida et al. (4,59,973) as applied to claim 51 above, further in view of Olinger et al. (3,941,121).

Hosaka et al. fails to show the probe comprises a needle with a distal optical system. However, Olinger et al. shows an analogous endoscope having a probe comprises a needle 11 with a distal optical system (Fig. 3). It would have been obvious to the artisan to further modify the noticed endoscope by forming the probe as taught by Olinger et al. since Olinger et al. teach that such would allow access to more areas of the body.

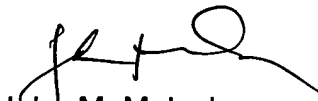
s. Claim 69 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hosaka et al. (EP 0,461,669) in view of Yoshida et al. (4,59,973) as applied to claim 66 above, further in view of Rossoff (5,183,031).

Hosaka et al. fails to show the cannula comprising a stylet. However, Rossoff shows an analogous endoscope having a stylet outer covering 12. It would have been obvious to the artisan to further modify Hosaka et al. by forming the cannula as a stylet since Rossoff suggests that such would allow the endoscopes use in intubation procedures.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John M. Mulcahy whose telephone number is (703) 308-3134. The examiner can normally be reached on M-F, 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. M. Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0873.



John M. Mulcahy
Primary Examiner
Art Unit 3739

John Mulcahy
June 29, 2003